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The Honorable Colleen McMahon  
United States District Court  
Southern District of New York  
500 Pearl Street, Room 2550  
New York, New York 10007

**Re: *In re Namenda Direct Purchaser Antitrust Litig.*, 15-cv-7488 (CM)**

Dear Judge McMahon:

At the Pretrial Conference on October 10, 2019, the Court instructed the Parties to discuss the admissibility of testimony from the patent technical experts and to submit a 5-page letter brief if necessary. ECF No. 889 at 27:3-8. Plaintiffs submit this letter brief in response to that instruction and respectfully request that this issue be resolved soon so that the Parties have a clear picture of which witnesses will be available during the trial. To the extent the Court is inclined to exclude testimony, Plaintiffs request oral argument given the importance of this issue.

Based on communications with Forest, it is “not trying to exclude these [two] witnesses in their entirety. . . .” 10-17-2019 Email String (Ex. 1) at 1. Instead, “Forest’s position is that the testimony of Herrmann [sic] and Schneider should be excluded *to the extent it is duplicative or cumulative of Johnston.*” *Id.* (emphasis added). Any dispute is moot because Plaintiffs absolutely commit not to duplicate testimony from any of these three witnesses. Instead, Drs. Herrmann and Schneider will offer abbreviated scientific and medical testimony on technical issues that impacted Mylan’s patent defenses. Mr. Johnston will pick up where Drs. Herrmann and Schneider leave off, explaining to the jury the implications of those technical issues on Mylan’s patent defenses and how he arrives at his estimates of likelihood of success. Mr. Johnston will therefore not duplicate Drs. Herrmann’s or Schneider’s testimony. The three direct examinations – all taken together – will total *approximately one day of trial time*. Plaintiffs expect that Forest will similarly commit that Forest’s patent expert Judge McKelvie will not duplicate the testimony of Forest’s technical experts despite the overlap in their expert reports.

The testimony of Drs. Herrmann and Schneider is particularly critical in this case. Forest will present evidence designed to create the Jury perception that Forest had a strong patent case: the reexamination of the ‘703 Patent, the claim construction decision in the Namenda Patent Litigation, and the subsequent settlements that occurred. Allowing the Jury to hear from Plaintiffs’ technical experts is crucial so that the Jury can put into perspective the handful of discrete scientific issues from the Namenda Patent Litigation, and understand that Mylan had presented very significant challenges to Forest’s 703 Patent despite Forest’s anecdotal evidence.

**I. Dr. Herrmann’s Testimony Is Highly Relevant and Non-Cumulative.**

Dr. Herrmann heads the Geriatric Psychiatry Division at the University of Toronto, where he holds the Richard Lewar Chair. Herrmann Report (Ex. 2) at 42-43 (CV). He is also the Co-Director of the Clinical Neuropharmacology Laboratory at the Sunnybrook Health Sciences Centre. *Id.* His testimony is essential to assist the Jury in understanding the science underlying Mylan's non-infringement defense, which was based on just two discrete issues. From the perspective of a skilled artisan in the field of the '703 Patent, he will explain why memantine – the active ingredient in Namenda – does not provide its therapeutic effect as an NMDA receptor antagonist at the relevant dosage levels. *Id.* ¶¶ 40-54. This requirement – that memantine act as an NMDA receptor antagonist – was required by the claim construction that Forest purportedly “won” in the Namenda patent litigation. Dr. Herrmann will clearly and concisely explain that various scientists – including Mylan's own expert, Dr. Olney – had performed studies and authored publications supporting the conclusion that the relevant dose of memantine did **not** produce its therapeutic effect by antagonizing NMDA receptors. *Id.* Dr. Herrmann will also explain that Forest had **no** evidence that Mylan's product met the construction of “effective amount,” yet another term Forest supposedly “won” at claim construction. *Id.* ¶¶ 79-81.

No other witness provides testimony like Dr. Herrmann's, or relies on the documentary foundation he relies upon. For example, the Court recognized at the pretrial conference the importance of PX-433, Dr. Olney's article written two years before the Namenda Patent Litigation. As the Court noted, such evidence could support a conclusion that Forest was concerned that studies from a respected scientist contradicted the mechanism of action required by the '703 Patent. ECF No. 889 at 99:11-22. Similarly, the Court recognized that another document (PX-436) was “plainly admissible” for the purpose of showing that “Forest was aware that it had made an admission, its top scientist had made an admission, that maybe, just maybe, the patent didn't work the way Forest said -- the way the claims said it had to work.” *Id.* at 102:25-103:10. Dr. Herrmann also addresses three other scientific articles (*i.e.*, PX-434, PX-435, and PX-437) supporting Mylan's position that the mechanism of action of memantine is different from that claimed in the '703 Patent. *Id.* ¶¶ 59-60. The Court has recognized that discrete statements from these articles, if relevant, can be read to the jury if Plaintiffs lays a foundation for the “learned treatise” exception at trial. ECF No. 889 at 98:8-10; 101:6-9; 103:11-25.

Mr. Johnston cannot possibly duplicate Dr. Herrmann's testimony because Mr. Johnston's expert report does not even mention these five scientific articles or list them among the references he reviewed. Johnston Report (Ex. 3). In light of the Court's ruling that portions of the above documents are probative and may be admissible if Plaintiffs can lay the appropriate foundation under the “learned treatise” exception, Dr. Herrmann is particularly important because Mr. Johnston – a nontechnical expert – cannot reasonably be expected to establish that these scientific articles are “reliable authority” under FRE 803(18). In addition, Dr. Herrmann is the key witness who can explain why Mylan's admitted ANDA documents – *e.g.*, DX-20, DX-402, DX-404, and PX-1217 – actually undercut rather than support Forest's infringement theory and raised very troubling issues for Forest in the Namenda Patent Litigation.

In short, Dr. Herrmann's testimony will provide the jury with a readily understandable explanation for why Forest agreed to pay Mylan tens of millions of dollars to avoid adjudicating the infringement issues. And it will also provide a summary of Mylan's technical evidence from which Mr. Johnston can explain his likelihood of success analysis.

## II. Dr. Schneider's Testimony Is Highly Relevant and Non-Cumulative.

Dr. Schneider is a Professor of Psychiatry, Neurology and Gerontology at USC and the Director of the California Alzheimer Disease Center at USC, the clinical core of the NIH-funded USC Alzheimer Disease Research Center. Schneider Report (Ex. 4) ¶ 3. He was hired by Forest in 2003 to present clinical evidence on memantine supporting Forest's new drug application for Namenda. *Id.* ¶ 7. Dr. Schneider's testimony is essential to helping the jury understand the science underlying Mylan's substantial invalidity defenses. From a skilled artisan's perspective, he will explain a handful of discrete scientific issues supporting Mylan's invalidity defenses.

No other witness provides testimony regarding the science relating to Mylan's invalidity defenses like Dr. Schneider, and no other witness relies upon and explains from a scientific perspective the impact of the particular documents which he addresses. For example, Dr. Schneider is the only witness who explains (1) why, if Forest was correct that Mylan's 20-mg dose of memantine achieved effects through NMDA receptor antagonism, then patients receiving the same memantine dose in prior art studies necessarily (*i.e.*, inherently) achieved the same effects; and (2) why, if Forest was correct that Mylan's 20-mg dose of memantine was an "effective amount," then the same dose was necessarily an "effective amount" in the prior art. *Id.* ¶¶ 75, 102. Dr. Schneider is also the key witness to explain – from the perspective of a person of skill in the art – that the same prior art references disclosing administering memantine to elderly patients diagnosed with "dementia" or "organic brain syndrome" or a related condition necessarily included "patient[s] diagnosed with Alzheimer's disease" as claimed in the '703 Patent. *Id.* ¶¶ 81-101. Dr. Schneider likewise discusses other issues, such as the workable dose in the '703 Patent and whether a person of skill in the art in 1989 would have accepted the hypothesis in the '703 Patent. *Id.* ¶¶ 135-42.

In addition, DX-492 and DX-495 are both prior art references to the '703 Patent that Forest has introduced into evidence. It is unfair for Forest to introduce this evidence while at the same time seeking to deny Plaintiffs' technical witness the opportunity to address it.

## III. Mr. Johnston's Testimony Will Be Neither Duplicative Nor Cumulative.

***Plaintiffs will not present duplicative testimony from any of their expert witnesses.*** It is of course true that Drs. Herrmann's and Schneider's scientific testimony relates to the same patent defenses that Mr. Johnston addresses from a patent lawyer's perspective. And to that extent, portions of their expert reports involve overlapping issues. As explained below, the same is true for Forest's experts. But Plaintiffs will carefully sculpt their trial examinations to ensure that Mr. Johnston picks up where Drs. Herrmann and Schneider leave off, rather than restating what they said. There will be ***no*** duplication. Drs. Herrmann and Schneider will testify and summarize a handful of discrete scientific issues supporting Mylan's defenses, whereas Mr. Johnston, a patent lawyer with expertise advising pharmaceutical clients regarding the likely outcome of patent litigation, will explain the significance of those scientific points and other evidence in terms of Mylan's patent defenses and its quantified likelihood of success.

## IV. Fundamental Fairness Counsels Against Excluding Dr. Herrmann or Dr. Schneider

The patent merits aspect of this antitrust case is largely a battle of Forest's anecdotal evidence versus Plaintiff's expert evidence. Forest argues there is "overwhelming objective evidence that Forest had a very strong patent case — including the reexamination to which the '703 patent was subjected prior to litigation, the presumption of validity attaching to all issued U.S. patents, and the successful claim construction rulings with the vast majority of generics settling soon thereafter. . . ." Forest's MSJ Brief (ECF No. 665) at 48. In response, Plaintiffs assembled a team of three experts whose combined testimony explains why Forest's anecdotal evidence did not suggest victory for Forest in the Namenda Patent Litigation. Drs. Herrmann and Schneider are vital components of that proof. It would be fundamentally unfair for Forest to present its anecdotal evidence while hindering Plaintiffs' response to that anecdotal evidence.

Given that Forest will advance its anecdotal evidence, Plaintiff should be permitted to respond to that evidence through its experts, who will put that evidence into perspective. For example, Dr. Herrmann will explain why the claim construction Forest obtained later became an anchor around its neck. *E.g.*, Ex. 2 ¶ 34. And Dr. Schneider will explain how the declaration of Dr. Weiner, one of Forest's medical doctor experts in the reexamination proceeding, provided strong scientific support for Mylan's argument that the claims were not enabled. Ex. 4 ¶ 137. Plaintiff's technical experts will put these issues into context and explain that Mylan had seized upon inconsistencies in Forest's positions and was ready to capitalize on those inconsistencies.

**V. Forest Has Waived the Right to Seek to Exclude Drs. Herrmann and Schneider, and Plaintiffs are Prejudiced By the Late Timing of the Request**

Forest asserted for the first time at the pretrial conference that the testimony of Drs. Herrmann and Schneider should be entirely excluded. To the extent Forest seeks only to preclude duplicative testimony, as Forest recently represented (*see* Ex. 1), no dispute exists. To the extent, however, Forest offers a different rationale in its letter brief, Forest has waived the argument. Forest (1) did not move under *Daubert* to exclude these experts; and (2) moved unsuccessfully to exclude specific aspects of Dr. Herrmann's testimony at the *limine* stage. MIL Order (ECF No. 859) at 7-9. Any eleventh-hour request to strike these experts is both late and unduly draconian. *See e.g. Cartier, Inc. v. Four Star Jewelry Creations, Inc.*, Civ. No. 01-cv-11295, 2003 WL 22471909, at \*1 (S.D.N.Y. Oct. 31, 2003) ("[E]xcluding expert testimony is a 'drastic remedy.'"). Further, the failure to timely raise these *Daubert*-like objections constitutes a waiver. *Hart v. BHH, LLC*, Civ. No. 15-cv-4804, 2019 WL 1494027, at \*1 (S.D.N.Y. Apr. 4, 2019) ("[T]hese are classic *Daubert* questions which could have been raised in the first *Daubert* motion. Accordingly, this Court construes Defendants' second motion *in limine* as an untimely *Daubert* motion in violation of this Court's scheduling order or as an untimely motion for reconsideration."); *United States v. Teva Pharm. USA, Inc.*, Civ. No. 13-cv-3702, 2019 WL 1245656, at \*12 (S.D.N.Y. Feb. 27, 2019) (McMahon, J.) ("As far as this court is concerned, the Parties have waived any *Daubert* arguments by not raising them at summary judgment. If I can consider an expert's [testimony] at summary judgment, a jury can consider it at trial.").

Plaintiffs have also been prejudiced by Forest's late request to strike Dr. Hermann's and Dr. Schneider's testimony. For example, Plaintiffs have proffered certain exhibits, and declined to object to otherwise objectionable Forest exhibits (especially certain Mylan documents) based on the understanding that Drs. Herrmann and Schneider would be able to rebut their asserted



significance at trial. If Drs. Herrmann and Schneider were excluded, fundamental fairness would require reassessing the admissibility of certain trial exhibits.

**VI. Any Exclusion of Drs. Herrmann or Schneider Would Necessitate Exclusion of Forest's Technical Experts, Drs. Malinow and Farlow**

Lastly, while Plaintiffs believe that they are entitled to the carefully-circumscribed testimony described above from Drs. Herrmann and Schneider at trial, in the event the Court excludes or curtails their testimony, the testimony of Forest's two technical experts (Dr. Malinow and Dr. Farlow) should necessarily be similarly excluded or curtailed.

At the pretrial conference, Forest's counsel stated that Forest intends to call Dr. Malinow as a witness who will testify about "Namenda." ECF No. 889 at 17:8-10. This is inaccurate. Dr. Malinow's expert report was submitted in response to the reports of Drs. Herrmann and Schneider. 2017 Malinow Report (Ex. 5) ¶¶ 19-22. In the underlying Namenda Patent Litigation, Dr. Malinow submitted expert reports on both infringement and validity. 2009 Malinow Report (Ex. 6) (validity); 2010 Malinow Report (Ex. 7) (infringement). In his 2017 report in this antitrust case, he (1) "incorporate[s] by reference [those prior reports] in their entirety"; and (2) states "I was prepared to testify as to those opinions in the '703 patent litigation and I have concluded that I am prepared to do so again in this case." Ex. 5 ¶ 18. Moreover, in his 2017 antitrust report, Dr. Malinow addresses whether the claims are "infringe[d]" (*id.* at p.6, subheading "B"); "anticipated" or "obvious" (*id.* ¶ 61); and "enabled" (*id.* ¶ 23).

The issue with regard to Dr. Farlow may be moot, as Forest advised the Court that it does not intend to call him at trial. ECF No. 889 at 29:16-19. In the underlying Namenda Patent Litigation, Dr. Farlow opined that none of Mylan's prior art references "anticipates" or renders "obvious" any of the '703 Patent claims. 2009 Farlow Report (Ex. 8) ¶¶ 18, 24. His 2017 report in this antitrust case (1) "incorporate[s] by reference" his prior report; and (2) states "[i]n general, my opinion is – as it was during the Namenda® patent litigation – that the claims of the '703 patent are neither obvious nor anticipated by any of the prior art references raised." 2017 Farlow Report (Ex. 9) ¶ 17.

Forest's patent litigation expert, Judge McKelvie, addresses the same infringement and validity defenses raised by Drs. Farlow and Malinow (although, like Plaintiffs' experts, from a different perspective). 2017 McKelvie Report (Ex. 10) ¶ 16. Indeed, he goes further by explaining how Drs. Malinow and Farlow "would have testified" in the Namenda Patent Litigation. *Id.* ¶ 78, 103. This is precisely the type of testimony that the Court held at the pretrial conference would be improper. ECF No. 889 at 98:23-99:6. It would be objectively baseless for Forest to seek to exclude Drs. Herrmann or Schneider while at the same time reserving the right to call Drs. Malinow and/or Farlow.

Respectfully submitted,



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